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REMARKS

With this Amendment claims 1-41 are pending in the application. Claims 8-28 have been withdrawn as being directed to non-elected subject matter. Applicant reserves the right to pursue these claims in subsequent divisional filings. New claims 36-41 are submitted. Claims 1-7 and 29-35 stand rejected.

Remarks Directed Towards Claim Rejections

Remarks Directed to Rejection of Claim 29 Under 35 U.S.C. 112, First and Second Paragraphs and Objection to the Specification Under 35 U.S.C. 112, Second Paragraph

Claim 29 stands rejected under 35 U.S.C. 112, first and second paragraphs and the specification is objected to under 35 U.S.C. 112, second paragraph for various reasons relating to use of the term "derivative" in claim 29. Applicant has amended claim 29 to delete the term "derivative" solely in order to clarify the claim since "derivative" is repetitive in that context.

In view of the amendment and these remarks, it is respectfully requested that the rejection of claim 29 under 35 U.S.C. 112, first and second paragraphs and the objection to the specification under 35 U.S.C. 112, second paragraph, relating to use of the term "derivative" be withdrawn.

Remarks Directed to Rejection of Claim 35 Under 35 U.S.C. 112, Second Paragraph

Claim 35 stands rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

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Specifically, claim 35 is cited as "failing to clearly set forth the metes and bounds of the patent protection desired" because it is believed that the phrase "acquired disorders" "fails to clearly define the subject matter encompassed by the instant claims." (Paper 9, p.6)

As set forth in the MPEP at 2173.02 regarding 35 U.S.C. 112, second paragraph:

> The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:
>
> (A) The content of the particular application disclosure;
>
> (B) The teachings of the prior art; and
>
> (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. If the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. 112, second paragraph is appropriate. In re Wiggins, 488 F.2d 538, 179 USPQ 421 (CCPA 1973).

In the instant case, the scope of the invention sought to be patented can be determined from the language of claim 35 with a reasonable degree of certainty where the term "acquired disorders" is used, in light of the disclosure, the prior art and the level of ordinary skill in the art to which the invention pertains.

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Firstly, the plain meaning of the term would be clear to one of skill in the art since the terms are those used in common language. According to the American Heritage Dictionary of the English Language, 4th Edition, the term "acquired" means:

1. Of or relating to a disease, condition, or characteristic that is not congenital but develops after birth.

2. Resulting from exposure to something, such as an antigen or antibiotic.

Further, the same source defines the term "disorder" as: "[a]n ailment that affects the function of mind or body."

Thus the combination of the ordinary meaning of the terms would be understood by one of ordinary skill to mean an ailment that affects the function of mind or body that develops after birth.

Secondly, the specification makes it clear that term "acquired disorders" refers to a cause of neuronal injury (claim 35). Thus, the ordinary use of the term "acquired disorders" and the specific use of the term in the specification combine to make it clear that "acquired disorders" is a limited class of non-congenital disorders that cause neuronal injury.

Finally, examples of "acquired disorders" are described in the specification and include diseases such as "multiple sclerosis, transverse myelitis, Parkinson's disease, CNS vasculitits and Alzheimer's disease." (instant specification, page 13, lines 16-18)

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Given the use of the term in the specification, the ordinary meaning of the term, and the examples listed, it is submitted one of ordinary skill in the art would be able to understand the scope of the invention as claimed.

In summary, Applicant submits that the present claim 35 is definite. In view of the above remarks, it is respectfully requested that the rejection of claim 35 under 35 U.S.C. 112, second paragraph, be withdrawn.

Remarks Directed to Rejection of Claim 35 under 35 U.S.C. 112, First Paragraph

Claim 35 is objected to under 35 U.S.C. 112, first paragraph as failing to teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure. The basis of the objection is that "only a limited number of "acquired disorders" examples are set forth" and that "these examples are neither exhaustive nor define the class of compounds required." (Paper 9, p.5)

In response, Applicant submits that it is not required that working examples be exhaustive. On the contrary, PTO guidelines explicitly state that representative examples suffice to enable a genus claim where one skilled in the art could practice the invention without undue experimentation. (MPEP, 8th Ed., 2164.02) In this case, Applicant believes that the term "acquired disorders" as used in the instant specification defines a genus that one of skill in the art would be able to understand in view of level of skill, state of the art and the information in the specification. In particular, determining whether a patient has an "acquired disorder" involves, for example,

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clinical examination to show the existence of a non-congenital disease. Such an examination requires basic clinical skills such as observation, history taking and laboratory testing, for example. Therefore, the term "acquired disorder" appears not to implicate undue experimentation since one of skill in the art would be able to determine whether a patient has an "acquired disorder" and such a determination is within the range of skills within the purview of the ordinary practioner.

Regarding the assertion that the claim is not enabled with respect to the term "acquired disorders" because the term does not "define the class of compounds required," Applicant submits that the class of compounds required is identified in claim 35. Claim 29, from which claim 35 depends, specifies administration of a non-steroidal, anti-inflammatory drug. Thus, there is no need for the term "acquired disorders" to implicate a class of drugs in order to enable the claim, since the claim itself identifies the class of drugs to be administered.

In summary, Applicant submits that claim 35 is enabled as required under 35 U.S.C. 112, first paragraph since the disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. In particular, the use of the term "acquired disorders" is enabled since no "undue experimentation" is required with regard to this aspect of the claimed invention.

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Remarks Directed to Rejection under 35 U.S.C. 102(b)

Claims 1, 5-7, 29, 32, 33, 34 and 35 were held to lack novelty under 35 U.S.C. 102(b) as being anticipated by Grilli et al.

In order for the cited reference to have anticipated Applicant's invention, the reference must teach every element of the claim. (MPEP, 8th Ed., 2131)

Grilli et al. are cited as teaching "the claimed non-steroidal anti-infammatory compounds..." (Paper 9, p.7)

Independent claim 1 has been amended to define over Grilli et al. by specifying that a method for treating neurotrauma according the present invention includes the step of administering an NSAID by intrathecal delivery (amended claim 1) and intraventricular delivery (new independent claim 36). Support for the amendment and new claims is found in the instant specification, inter alia, at page 20, line 15 – page 25, line 15. In contrast to the present invention, Grilli et al. does not teach the intrathecal administration of an NSAID. Thus, it is submitted that independent claim 1 and claims 5-7 depending therefrom are not anticipated by Grilli et al. under 35 U.S.C. 102(b), since the reference does not teach every element of the claims.

Independent claim 29 and claims 32-35 depending therefrom stand rejected as anticipated by Grilli et al. under 35 U.S.C. 102(b) because the references teaches "the claimed non-steroidal anti-infammatory compounds..." (Paper 9, p.7) However, independent claim 29 includes the limitation that the claimed method includes "intrathecally administering" an NSAID. Applicant submits that Grilli et al. does not appear to teach intrathecal administration and that therefore Grilli

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et al. does not teach every element of claim 29. Further, since the limitations of the independent claim are deemed to be present in claims depending from the independent claim, Applicant submits that dependent claims 32-35 are likewise not anticipated by Grilli et al.

On the basis of these arguments and the amendment of claim 1, it is submitted that claims 1, 5-7, 29, 32, 33, 34 and 35 are not anticipated under 35 U.S.C. 102(b) by Grilli et al. Thus, it is respectfully requested that the rejection of claims 1, 5-7, 29, 32, 33, 34 and 35 as anticipated by Grilli et al. be withdrawn.

Remarks Directed to Rejection under 35 U.S.C. 103 - Grilli et al. in view of the Merck Index

Claims 1, 4-7, 29 and 31-35 are held to be unpatentable under 35 U.S.C. 103 as being obvious over Grilli et al. in view of the Merck Index.

> To establish a prima facie case of obviousness...the prior art reference (or references when combined) must teach or suggest all the claim limitations. (MPEP, 8th Ed., 2143)

The combination of Grilli et al. is cited as teaching NSAIDS detailed in claims 1, 5-7, 29 and 32-35 except for a "specific recitation of the claimed medicaments" in claims 4, 31 and 32. (Paper 9, pp.7-8) It is asserted that "[t]his deficiency is cured by the Merck Index teaching Choline salicylate as an old and well known NSAID." (Paper 9, p. 8)

Dependent claims 4 and 31 describe a method wherein the NSAID comprises choline magnesium trisalicylate. Applicant submits that the cited Merck Index entry for "choline

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salicylate" does not appear to describe choline magnesium trisalicylate. Applicant notes that choline salicylate is described as $C_{12}H_{19}NO_4$, that is, containing no magnesium. In addition, the Merck Index entry does not appear to describe a trisalicylate. Since, as noted by the Examiner, the Grilli et al. reference does not appear to describe choline magnesium trisalicylate either, Applicant submits that the combination of Grilli et al. and the Merck Index does not establish a prima facie case of obviousness regarding claims 4 and 31 because not all the claim limitations are present in the references .

Applicant further notes that since claims 1, 4-7, 29 and 31-35 include the limitation that an NSAID is delivered by intrathecal administration, no prima facie case of obviousness is established on the basis of Grilli et al. in view of the Merck Index since neither reference describes intrathecal administration of NSAIDS as does the instant application.

In view of these remarks and claim amendments, it is respectfully requested that the rejection of the pending claims under 35 USC 103(a), over Grilli et al in view of the Merck Index, be withdrawn.

Remarks Directed to Rejection under 35 U.S.C. 103 - Grilli et al. in view of the Merck Index and further in view of Jurna et al. and Sakanashi et al.

Claims 2, 3 and 30 are held to be unpatentable under 35 U.S.C. 103 as being obvious over Grilli et al. in view of the Merck Index and further in view of Jurna et al. and Sakanashi et al.

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Jurna et al. and Sakanashi et al. are cited as teaching "administration via the interthecal and by intercoronary injection." (Paper 9, p. 8-9) Based on the combination of Grilli et al., the Merck Index, Jurna et al. and Sakanashi et al., it is asserted that "[t]he skilled artisan would have seen interthecal and inter-coronary routes as residing in the skilled artisan purview." (Paper 9, p.9)

Applicant notes that claims 2 and 3 have been cancelled and the limitations of claims 2 and 3 have been incorporated into claim 1 and new claim 36 respectively.

> To establish a prima facie case of obviousness... there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. (MPEP, 8th Ed., 2143)

Grilli et al. is cited as teaching NSAIDs but lacking as to any teaching of intrathecal or intraventricular adminstration (Paper 9, p. 8-9) Jurna et al. is described as "employ[ing] NSAID compounds by the interthecal" route. (Paper 9, p.9) However, Applicant submits that one of skill in the art would not be motivated to combine the reference teachings.

The Jurna et al. reference presents results of in-vivo experiments showing that three NSAIDs produce similar effects when administered to rats intrathecally, that is, "intrathecal injection of acetylsalicylic acid, salicylic acid and indomethacin depresses C fibre-evoked activity in the rat thalamus and spinal cord." (Jurna et al., abstract title) In contrast to this, the Grilli et al. reference shows strikingly diverse effects of acetylsalicylic acid, salicylic acid and indomethacin when these NAIDS are administered directly to cultured neurons. (Grilli et al., Table 1)

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It is well-settled case law that: "conflicting teachings can not reasonably be viewed as suggesting their combination" Karsten Mfg. Corp. v. Cleveland Golf Co. 242 F.3d 1376; 58 U.S.P.Q.2D 1286

Applicant submits that the differences in NSAID action in the two references would not reasonably be viewed by one of skill in the art as suggesting the combination of these references. In fact, association of a different drug effect with a different route of administration may be viewed as a contraindication regarding the new route. Applicant therefore believes that a prima facie case of obviousness is not established since no suggestion of combining the references can reasonably be established. It is respectfully requested that this rejection of claims held to be unpatentable under 35 U.S.C. 103 as being obvious over Grilli et al. in view of the Merck Index and further in view of Jurna et al. be withdrawn.

Sakanashi et al. is cited as teaching "inter-coronary injection" and indeed, the reference describes response of dog coronary arteries to various agents. However, Applicant submits that the instant invention does not teach administration of NSAIDs to ventricles of the heart, but rather to the ventricules of the brain. Thus, Applicant's use of the term "intraventricular" refers to administration "directly into the cerebrospinal fluid (CSF) of a person." (instant specification, p. 12, lines 21-22.)

To establish a prima facie case of obviousness...the prior art reference (or references when combined) must teach or suggest all the claim limitations. (MPEP, 8th Ed., 2143)

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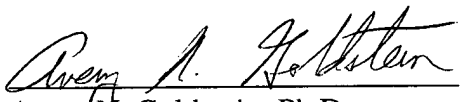
Applicant submits that the combination of Grilli et al. in view of the Merck Index and further in view of Sakanashi et al. does not render instant claims unpatentable as obvious under 35 U.S.C. 103 since none of the references, nor the combination of the references, teaches or suggests the claim limitation of intraventricular administration. Applicant respectfully requests withdrawal of the rejection of claims held to be unpatentable under 35 U.S.C. 103 as being obvious over Grilli et al. in view of the Merck Index and further in view of Sakanashi et al.

Summary

Claims 1-41 are the pending claims in this application. Claims 8-28 have been withdrawn from consideration. New claims 36-41 are submitted herewith. Each claim is believed to be in

proper form and directed to allowable and patentable subject matter. Reconsideration and allowance of the claims is requested.

Respectfully submitted,



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